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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/101,413	08/07/98	STAUSS	H RPMS102

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EXAMINER	
LUBET, M	
ART UNIT	PAPER NUMBER
1644	8
DATE MAILED:	08/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

## Office Action Summary

Application No.  
09/101,413

Applicant(s)

Strauss

Examiner

Lubet

Group Art Unit

1644



Responsive to communication(s) filed on Aug 7, 1998

- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.
- A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

### Disposition of Claims

- Claim(s) 1-18, 20-43, and 45-49 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) \_\_\_\_\_ is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims 1-18, 20-43, and 45-49 are subject to restriction or election requirement.

### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- \*Certified copies not received: \_\_\_\_\_.
- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

... SEE OFFICE ACTION ON THE FOLLOWING PAGES ...

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1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.  
In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 41-43, drawn to CTL lymphocytes.

Group II, claim(s) 1-18, drawn to a method of treating a patient by administering CTL of Group I.

Group III , claim(s) 20-40, drawn to a method of making a clonal population of CTL.

Group IV, claim(s) 45, drawn to a library of CTL clones.

Group V, claim(s) 46, drawn to therapeutic system comprising a means to determine HLA class and a library of CTL clones .

Group VI, claim(s)47 and 48, drawn to a method of making a CTL by introducing a genetic construct encoding a TCR of a CTL into a CTL or CTL precursor and CTL made by said method.

Group VII, claim(s) 49, drawn to a method of treating a patient by administering the CTL of Group VI.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: .

3. The special technical feature of Group I-III is CTL lymphocyte.

The special technical feature of Groups IV library of CTL clones

The special technical feature of Group V is a kit comprising a means to determine MHC class I haplotype and a library of CTL clones.

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The special technical feature of Group VI-VII is a CTL made by introducing a genetic construct, IE vector, encoding a TCR of a CTL.

The inventions of Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because they lack the same or corresponding special technical feature for the following reasons.

Melief et al. US 5,731,160 teaches a clonal population of cytotoxic T cells produced by culturing CTL precursors with stimulator cells which express HLA Class I loaded with a particular peptide ( see abstract, claims 1-10 and column 7, line 6 through column 12, line 25, in particular). Therefore the special technical feature linking Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the art. Accordingly Groups I-VII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

4. If Applicant elects any of I-V or VII, Applicant is further required to elect a particular species.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1-19, 20-43, 45-50.

The species are as follows:

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Groups II and VII are drawn to a plurality of methods of treating a disease by administering a particular CTL. Applicant is required to elect a specific embodiment of the invention by electing a particular disease (IE breast cancer) and a particular antigen to which the CTL are specific (IE ERB-2).

Groups III is drawn to a plurality of methods of making a CTL clone. Applicant is required to elect a particular embodiment of the claimed method. Applicant is required to elect a molecule to which the CTL are reactive (IE ERB-2)a particular stimulator cell used in the claimed method (Drosophila cell) and a costimulator molecule expressed in the stimulator cell (IE ICAM-1).

Group V is drawn to a plurality of therapeutic systems. Applicant is required to elect a particular embodiment of the claimed therapeutic system. Applicant is required to elect a particular means of determining HLA class I type and a antigen for which the CTL are specific.

4. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:.. Each CTL of Groups I and IV has distinct function and characteristics, IE is specific for different peptides. Each embodiment of the methods of Groups II, III and VII are practiced with materially different products.. Each embodiment of the therapeutic system of Group V have different components which are biochemically and functionally distinct.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Martha Lubet in Art Unit 1644 whose telephone number is (703) 305-7148. The examiner can normally be reached on Monday through Friday from 8:15 AM to 4:45 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at (703) 3053973. The FAX number for this group is (703) 305-3014. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Martha T. Lubet

THOMAS M. CUNNINGHAM  
PRIMARY EXAMINER  
GROUP 1800